This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
Date Prepared: August 15, 2001

510(k) number: K012749

JAN 2 4 2002

Applicant Information:
BioCardia, Inc.
384 Oyster Point Blvd. #6
South San Francisco, CA 94080

Contact Person: Daniel C. Rosenman
Phone Number: (650) 624-0120
Fax Number: (650) 624-0125

Device Information:
Classification: Class II
Trade Name: BioCardia Universal Deflectable Guide Catheter
Classification Name: Percutaneous Catheter (21 CFR 870.1250)

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the SCIMED Triguide Guide Catheter (K961280), the USCI Mainstay Guiding Catheter (K971034) and the Cardima Naviport Deflectable Tip Guiding Catheter (K974683).

Intended Use:
The BioCardia Universal Guide Catheter is intended to serve as a conduit for access into the chambers of the heart and coronary vasculature of the heart.

Test Results:
Performance
Results of in-vitro and animal testing demonstrate that the BioCardia Universal Deflectable Guide Catheter is safe and effective for its intended use.

Biocompatibility
The materials used in the BioCardia Universal Deflectable Guide Catheter are identical to those used in other diagnostic catheters and meet the requirements of ISO 10993-1.

Summary: Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2002

Mr. Daniel C. Rosenman
Vice President, Research & Development
BioCardia, Inc.
384 Oyster Point Boulevard, Suite #4
South San Francisco, CA 94080

Re: K012749
Trade Name: BioCardia Universal Deflectable Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: 74 DQO
Dated: November 2, 2001
Received: November 5, 2001

Dear Mr. Rosenman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K012749

Device Name: BioCardia Universal Deflectable Guide Catheter

Indications for Use:

The BioCardia Universal Deflectable Guide Catheter is intended to serve as a conduit for access in the chambers and coronary vasculature of the heart

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012749

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)